Remarks/Arguments

Information Disclosure Statement

The Examiner is respectfully requested to return to the undersigned a copy of the IDS Form filed on April 29, 2011, with an indication thereon that all the cited documents were considered and made of record.

Applicants' Presently Claimed Invention

Applicants' present claims are directed to a prostaglandin-containing product comprising an aqueous liquid preparation containing a prostaglandin F2α derivative having a fluorine atom or fluorine atoms in a molecule and a resin container containing the aqueous liquid preparation, the resin container being formed from a polymer alloy of polyethylene terephthalate and polyarylate, wherein a component ratio of polyethylene terephthalate/polyarylate is ½ to 2/1, thereby inhibiting the decrease of the content of the prostaglandin F2α derivative in the aqueous liquid preparation.

The presently claimed invention, as described in "Disclosure of the Invention" and the "examples" in the present

specification, takes into account the material that a container for an eye drop is made of, and is based on the finding that a decrease of the content of a prostaglandin F2α isopropyl ester contained in the container can be significantly inhibited. This significant inhibition is brought about by storing a prostaglandin F2α derivative, such as 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2α isopropyl ester, in a resin container formed from a polymer alloy of polyethylene terephthalate and polyarylate, wherein a component ratio of polyethylene terephthalate/polyarylate is ½ to 2/1 (for example, wherein said component ratio is 45/55 as disclosed at the middle of page 12 of the present specification).

Rejection Under 35 USC 103

Claims 12 and 14 were rejected under 35 USC 103 as being unpatentable over Morishima et al. (WO 02/22131 (US 2004/0097592 being used as a translation)) in view of Koide et al. (JP 7-33650) for the reasons set forth beginning at the middle of page 3 and continuing to the middle of page 5 of the Office Action.

The Morishima et al. reference was cited to teach prostaglandin F2α derivatives. However, it was admitted in the Office Action that Morishima et al. do not specifically teach a resin container containing a copolymer of polyethylene terephthalate and polyarylate with a ratio of 1:2 to 2:1.

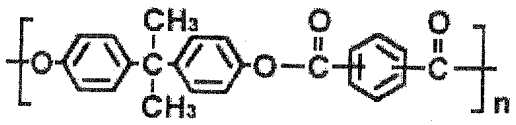
The Koide et al. reference was cited with respect to a resin container and a generic disclosure of inhibiting photolysis and adhesion of vitamin A to the container.

It was also admitted in the Office Action that the references do not specifically teach adding the ingredients in the ratio as claimed by the applicants.

The position was taken in the Office Action that paragraph [0014] of Morishima et al. teaches "polyethylene terephthalate" and "acrylic resins." However, "acrylic resins" are resins comprising a polymer of acrylic acid or acryl ester (CH_2=CHCOOR, R=H, alkyl and the like). Typical acrylic resins are polyacrylic acid and polyacrylic ester.

On the other hand, "polyarylate" is a polymer represented by the following formula which differs completely from the structure of "acrylic resins." Thus, "acrylic resins" and "polyarylate" as

recited in applicants' present claims, are completely different resins.



(polyarylate)

As seen from the above, Morishima et al. do not teach or suggest "polyarylate or a polymer alloy of polyethylene terephthalate and polyarylate.

Although Morishima et al. and the present invention share the same object to inhibit the absorption of prostaglandin derivatives to a container, since Morishima et al. require an addition of a nonionic surfactant or an antioxidant to inhibit the absorption, while the presently claimed invention involves storage in a container for eye drops made of a polymer alloy of polyethylene terephthalate and polyarylate, Morishima et al. and the presently claimed invention completely differ in the means of achieving the object.

The position was taken at the bottom of page 4 of the Office Action that it would have been obvious to a person of ordinary skill in the art to incorporate the compositions disclosed by Morishima et al. into a resin container of Koide et al. comprising polyethylene terephthalate and polyarylate.

However, as is clear from the claims and paragraph [0008] of Koide et al., Koide et al. relate to an aqueous eye drop solubilizing Vitamin As characterized by storing the Vitamin As in a container made of polyethylene terephthalate containing (1) a pigment or (2) pigments and a U-polymer, wherein a pigment is an essential component and a U-polymer (polyarylate) is an optional component.

According to the examples of Koide et al. (stability test using white florescent light), Examples 1 and 2 in Table 1 shows that when vitamin A palmitate is stored in a resin container comprising polyethylene terephthalate containing a pigment, the concentration (residual ratio) of the Vitamin A are respectively 89% and 99%, and the Vitamin A palmitate is stable. Meanwhile, Comparative Example 4 of Table 2 of Koide et al. shows that when vitamin A palmitate is stored in a resin container comprising polyethylene terephthalate containing a U-polymer (polyarylate)

but NOT a pigment, the concentration (residual ratio) of the vitamin A is merely 26%, and the Vitamin A palmitate is not stable at all.

In other words, the Comparative Example 4 in Table 2 of Koide et al. shows that even if Vitamin A is stored in a resin container comprising polyethylene terephthalate containing a U-polymer (polyarylate), the Vitamin A is not stabilized.

On the other hand, as is clear from applicants' Example, the presently claimed invention shows that storing "a prostaglandin F2α derivative having a fluorine atom or fluorine atoms in a molecule" in a container made of polyethylene terephthalate and polyarylate without any pigment inhibits the absorption of the prostaglandin F2α derivative and exhibits significant storage stability of "the prostaglandin F2α derivative having a fluorine atom or fluorine atoms in a molecule."

A pigment is an essential component of Koide et al. to stabilize "Vitamin As", whereas the presence of a pigment is not an essential requirement to inhibit the absorption of "a prostaglandin F2α derivative having a fluorine atom or fluorine atoms in a molecule" which is stable in light and liable to be absorbed on a container in the presently claimed invention. This

comes from the fact that Vitamin As and a prostaglandin F2α derivative having a fluorine atom or fluorine atoms in a molecule are different in their chemical structures and chemical properties. Therefore, Koide et al. and the presently claimed invention completely differ from each other.

As discussed above, Koide et al. is characterized by storing Vitamin A in a resin container comprising polyethylene terephthalate containing a pigment, and shows in Comparative Example 4 in Table 2 that the Vitamin A is not stabilized at all when stored in a resin container comprising polyethylene terephthalate and polyarylate. In view of the foregoing, one of ordinary skill in the art may consider incorporating the composition of Morishima et al. into a resin container comprising polyethylene terephthalate containing a pigment. However, one of ordinary skill in the art would not consider incorporating the composition of Morishima et al. into a resin container comprising polyethylene terephthalate and polyarylate.

As discussed above, Koide et al. require a pigment as an essential component, and according to the examples (stability test using white florescent light) therein, the concentration (residual ratio) of the Vitamin A palmitate in Comparative

Example 1 in Table 1 and Comparative Example 4 in Table 2, wherein the resin does not contain a pigment, are respectively 0% and 26%. Thus, a Vitamin A stabilizing effect is not established at all.

As seen from the above, no stability effect of vitamin As is exhibited when the Vitamin As is stored in a container comprising polyethylene terephthalate without a pigment (Comparative Example 1) or a container comprising polyethylene terephthalate containing polyarylate without a pigment (Comparative Example 4) in Koide et al. In contrast thereto, in the presently claimed invention, the absorption of "a prostaglandin F2α derivative having a fluorine atom or fluorine atoms in a molecule" to a container is inhibited. Furthermore, a significant stability effect is established in the presently claimed invention.

Accordingly, incorporating the composition of Morishima et al. into the container of Koide et al., which requires "a pigment" as an essential component, teaches away from the presently claimed invention, wherein a prostaglandin F2α derivative having a fluorine atom or fluorine atoms in a molecule in a container comprising a polymer alloy of polyethylene terephthalate and polyarylate, without a pigment.

Withdrawal of the 35 USC 103 rejection is respectfully requested.

Reconsideration and allowance of the above-identified application are respectfully solicited.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,

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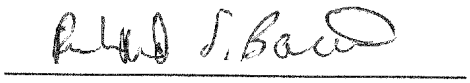

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